

February 3, 2022

Omnisonics Medical Technologies  
Anne Kulis  
Vice President  
66 Concord Street, Suite A  
Wilmington, Massachusetts 01887

Re: K071762

Trade/Device Name: Omniwave Endovascular System  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Embolectomy catheter  
Regulatory Class: Class II  
Product Code: QEY, KRA

Dear Anne Kulis:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 27, 2007. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, [Gregory.Oconnell@FDA.HHS.gov](mailto:Gregory.Oconnell@FDA.HHS.gov).

Sincerely,

**Gregory W.**  
**O'Connell -S**

Digitally signed by  
Gregory W. O'Connell -  
S  
Date: 2022.02.03  
14:27:47 -05'00'

Gregory O'Connell  
Assistant Director  
DHT2C: Division of Coronary  
and Peripheral Intervention Devices  
OHT2: Office of Cardiovascular Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 27 2007

OmniSonics Medical Technologies, Inc.  
c/o Ms. Anne M. Kulis  
Vice President Quality, Regulatory & Clinical Affairs  
66 Concord Street  
Wilmington, MA 01887

Re: K071762  
OmniWave Endovascular System  
Regulation Number: 21 CFR 870.1210  
Regulation Name: Continuous Flush Catheter  
Regulatory Class: Class II (Two)  
Product Code: KRA  
Dated: August 31, 2007  
Received: September 4, 2007

Dear Ms. Kulis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Section 4

### Indications for Use

510(k) Number (if known): K071762

Device Name: Omnisonics Omniwave Endovascular System

Indications For Use:

The Omniwave Endovascular System is indicated for use in the infusion of physician specified fluids, including thrombolytics, into the peripheral vasculature and for removal of thrombi from the peripheral vasculature.

Prescription Use X

AND/OR

Over-The-Counter Use     

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Danna R. Vachon  
Division Sign-Off  
Division of Cardiovascular Devices  
510(k) Number K071762

000011

## Section 5

SEP 27 2007

### 510(k) Summary Omnisonics Omniwave Endovascular System

**510(k) Number:** K071762

**Submitter:** OmniSonics Medical Technologies, Inc.  
66 Concord Street  
Wilmington, MA 01887  
Phone: 978-657-9980  
Fax: 978-657-9982

**Contact Person:** Anne M. Kulis  
Vice President Quality, Regulatory & Clinical Affairs

**Date Prepared:** June 29, 2007

**Trade Name:** Omniwave Endovascular System

**Classification Name:** CFR §870.1210, Catheter, Continuous Flush

**Predicate Devices:**

1. Bacchus Trellis®-8 Peripheral Infusion System – K050147
2. KPS Rinspiration™ System – K050130
3. EKOS Lysus® Infusion Catheter System – K050563
4. Omnisonics Resolution® Endovascular System – K052428

**Device Description:**

The Omniwave Endovascular System is comprised of two major components: (1) the sterile, single use Kit, and (2) the multi-use Generator.

**Intended Use:**

The Omniwave Endovascular System is indicated for use in the infusion of physician specified fluids, including thrombolytics, into the peripheral vasculature and for removal of thrombi from the peripheral vasculature.

000012

**Summary of Technological Characteristics of the Applicant Device Compared to the Predicate Device:**

There are no significant technological differences between the applicant device and the predicate devices. The technological characteristics of the applicant device are substantially equivalent to the predicate devices with respect to device classifications, intended use, indications for use, target population, product design, materials, packaging, labeling, sterilization and product performance.

**Support of Substantial Equivalence:**

Both the applicant and predicate devices treat the same patient population and have the same intended use and indication for use. Product testing has demonstrated that the applicant device is substantially equivalent to the predicate devices.

**Conclusion:**

The Omniwave Endovascular System is substantially equivalent to the predicate devices.